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(54) Title: MONOCLONAL ANTIBODY BASED BIOMARKER DISCOVERY AND DEVELOPMENT PLATFORM

## BIOMARKER DISCOVERY PLATFORM

Collection of analytes: e.g., plasma samples Enrichment for, e.g., low abundance and specific proteins
Generation of hybridoma supernatants (mAb candidates)
Prevalidation: biomarker hit generation via throughput screening of hybridoma supernatants (mAbs)
Large scale protein ID by nanovolume integrated mass spectrometry
Bioinformatics, bioanalysis, hypothesis building, candidate selection for further validation steps - data integration
Biomarker lead generation: screening on clinical collection

(57) Abstract: A method or platform for monoclonal antibody based biomarker discovery is disclosed. The method according to the invention provides for the integration of analyte collection, hybridoma screening and nanovolume integrated mass spectrometry (NVIMS) to achieve a robust screening system that is capable, for example, of cutting 4-6 years off of the classical biomarker discovery and development process. The invention provides a platform for the rapid, high-throughput production, isolation and characterization of, e.g., disease specific biomarkers together with highly specific monoclonal antibodies. The method of the invention has a variety of applications such as, but not limited to, drug testing, biohazard applications, ecological applications, physiological applications and/or pathology screening applications. The method of the invention is also capable of being performed or used as or with a high-throughput screening process or system of the invention.

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